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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,183	01/26/1999	NORDINE CHEIKH	16517.228	9529

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/237,183

Applicant(s)

CHEIKH ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2 and 7-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 7-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' response, filed 25 August 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 2 and 7-27 are currently pending. Claims 1 and 3-6 have been cancelled.

#### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 7-27 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility.

#### ***Response to Applicant's Arguments***

1. Applicant argues that the disclosed nucleic acid molecules provide at least one specific benefit to the public, for example, use to encode a sucrose pathway enzyme or fragment thereof.

As stated previously, this is not persuasive, as use to encode a sucrose enzyme or fragment thereof supports the requirement for further research in order to establish a patentable utility since such a use is clearly a research project without defining any specific or substantial utility for any sucrose pathway genes that may be identified. Additionally, the specification lacks specific procedures for performing the use and thus also failing to provide a utility in currently available form.

Art Unit: 1631

2. Applicant further argues that “the claimed nucleic acid molecules provide identifiable benefits, for example, use to encode triose phosphate, fructose 1,6-biphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, frustokinase, NDP-kinase, or UDP-glucose pyrophosphorylase as nucleic acids markers and probes; to identify and obtain nucleic acid homologues; in microarray as gene specific targets; to identify the presence or absence of a polymorphism; use to transform plants; to determine the level or pattern of expression of a protein or mRNA associated with that nucleic acid molecule; and use to overexpress or suppress one or more of these coding sequences in a transgenic plant”.

This is not persuasive. The claims do not have a specific asserted utility because the disclosed uses of these compositions are not specific to the claimed nucleic acids and are generally applicable to any nucleic acid. The research contemplated by applicant(s) to discover genes does not constitute a specific and substantial utility. Potential uses for nucleic acid homologue identification, for example, do not provide an immediate benefit. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic acids.

3. Applicant states that the “Examiner appears to challenge the credibility of the presently asserted utilities” and that the “Examiner must set forth factual reasons which would lead one of skill in the art to question the objective truth of the statement of operability”. Applicant’s assert that the “Examiner has not even attempted to meet this burden” and instead “the Examiner merely asserts that sequence similarity does not reliably correlate to structural similarity”.

Art Unit: 1631

This is not persuasive. As has been set forth previously and is maintained herein, the Examiner **has** provided factual evidence, in the form of several publications documenting the unpredictability of the relationship between sequence, structure, and function. (see previous Office Action at page 5). Therefore, the Examiner's statements are not mere assertion.

Further, Applicant is reminded that a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. See *In re Fisher*, 421 F.3d at 1374, 76 USPQ2d at 1232 ("Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.... Nothing about [applicant's] seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the [ ] application or indeed from any EST derived from any organism. Accordingly, we conclude that [applicant] has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.").

Further, Applicant is reminded that the application must show that a claimed invention has a significant and presently available benefit to the public." *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230. The claims at issue in *Fisher* were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. This is analogous to the instantly claimed sequences. The court held that "the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant's] research effort, but only tools to be used along the way in the search for a practical utility.... Finally, a "substantial utility" defines a "real world" use. Utilities that require

Art Unit: 1631

or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. Therefore, the rejection is hereby maintained.

Claims 2 and 7-27 also remain rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and/or substantial utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The rejection is maintained for the reasons set forth in the Utility rejection above.

### **Conclusion**

No claims are allowed.

The outstanding rejection under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn in view of the amendment to claim 2, canceling “fragment of said enzyme”.

The outstanding rejections under 35 USC 102 have been withdrawn in view of the amendment to claim 2, canceling “fragment of said enzyme”.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1631

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

November 4, 2006  
Lori A. Clow, Ph.D.  
Art Unit 1631

*Lori A. Clow*  
*Patent Examiner*  
*11/4/06*